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No. 10-426

Supreme Court, U.S.
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IN THE
# Supreme Court of the United States

APPLERA CORP. AND TROPIX, INC.,
*Petitioners,*

v.

ENZO BIOCHEM, INC., ENZO LIFE SCIENCES, INC., AND YALE UNIVERSITY,
*Respondents.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## SUPPLEMENTAL BRIEF

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## SUPPLEMENTAL BRIEF

If the Federal Circuit actually used the indefiniteness standard that the United States articulates, we would not be here today. The government recognizes that the Patent Act "requir[es] that patent claims provide clear notice of the metes and bounds of the patented invention." U.S. Br. 8. Strikingly, this is the same legal standard articulated by Applera, and it is grounded in this Court's precedents holding that the inventor must specify the invention's boundaries so that the public can understand precisely what is reserved to the patentee, Pet. 16-18. The government, however, misapprehends the Federal Circuit's actual practice. The problem is not "phrases" that are troubling "in isolation," U.S. Br. 13, nor the occasional "misapplication" of a correct legal standard, *id.* at 15. What is required is a course correction: The Federal Circuit does not remotely require the "clarity," "precision" and "particular[ity]" that this Court has recognized the Patent Act demands. This error has given rise to a fundamental imbalance in the patent system. Because the Federal Circuit almost always finds patent claims definite under its toothless standard, there exists a substantial incentive for patentees to draft their claims broadly and vaguely. The result—as Judge Plager explains, and Professor Lemley confirms on behalf of leading innovators—is that competition is stifled. Pet. App. 76a n.2; Altera Br. 11 & n.3, 13, 15-17. This is the very "zone of uncertainty" that the Court has warned of. *United Carbon* v. *Binney & Smith*, 317 U.S. 228, 236 (1942). It is this essential malfunction—and not some quibble about terminology—that cries out for correction.

## I. THE FEDERAL CIRCUIT HAS DEPARTED FROM THE TEXT OF § 112 AND THIS COURT'S PRECEDENTS CONSTRUING IT.

For more than a century, the Court has recognized that the Patent Act demands "clarity," "precision" and "particular[ity]" in patent claims. 35 U.S.C. § 112 ¶ 2 ("particularly pointing out and distinctly claiming"); *Markman* v. *Westview Instrs.*, 517 U.S. 370, 390 (1996) (public must be "'clearly told what ... limits [its] rights'"); *The Incandescent Lamp Patent*, 159 U.S. 465, 475 (1895) ("'clearness and precision'"); see Pet. 16-18 (citing cases). Far from disputing these standards, the United States reiterates them. U.S. Br. 8.

The Federal Circuit's test resides at the other end of the claiming spectrum. See Pet. 18-21. Rather than requiring "clarity" and "precision," the Federal Circuit says that a claim is indefinite "only if reasonable efforts at claim construction *prove futile*." *Exxon Research & Eng'g* v. *United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (emphasis added). Alternatively: "Only claims 'not amenable to construction' or 'insolubly ambiguous'"—that is, whose terms "*can[not] be given any reasonable meaning*"—"are indefinite." *Datamize* v. *Plumtree Software*, 417 F.3d 1342, 1347 (Fed. Cir. 2005) (emphasis added). The government sheepishly acknowledges the error in the Federal Circuit's jurisprudence:

> Read in isolation, those phrases ["capable of construction" and not "insolubly ambiguous"] might suggest an insufficiently demanding definiteness standard to a district court looking for guidance. At least in the main run of its decisions, however, the Federal Circuit has used those phrases to express principles that are well grounded in this Court's Section 112 jurisprudence.

U.S. Br. 13; *accord id.* at 15. Not only "might" the Federal Circuit's cases "suggest" an erroneous standard—the United States previously has recognized that they do just that. It has compared the Federal Circuit's leading indefiniteness case unfavorably with this Court's cases,[1] and the Federal Trade Commission criticized "the 'insolubly ambiguous' standard" for "accept[ing] substantial ambiguity."[2] The government's recognition that the court of appeals with exclusive jurisdiction over patent cases employs a test that may mislead district courts is proof positive that this Court should grant review.

The government nonetheless says that certiorari should be denied because the Federal Circuit is using this "imprecise language" as a stand-in for correct "principles"—not always, but "in the main run of its decisions." U.S. Br. 12-13. In fact, the Federal Circuit's rule conflicts directly with "this Court's Section 112 jurisprudence." The United States devotes multiple pages to showing that the Federal Circuit correctly articulates certain claim-construction principles, both in general, *id.* at 8-9, and in this case, *id.* at 11, 15 (quoting Pet. App. 11a). But rules of claim construction are not at issue here; this petition asks the Court to review the Federal Circuit's erroneous understanding of indefiniteness. And, at least since the Federal Circuit announced its "insolubly ambiguous" test in 2001, see *Exxon Research*, 265 F.3d at 1375,[3] that court has required minimal determinacy

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[1] *See* Pet. 25 (quoting U.S. amicus brief in *Ariad Pharm.* v. *Eli Lilly*).

[2] *The Evolving IP Marketplace* 11 (Mar. 2011), *available at* http://www.ftc.gov/os/2011/03/ 110307patentreport.pdf.

[3] The government's reliance on earlier Federal Circuit cases, Br. 12-13, therefore is beside the point.

in patent claims. Its test cannot be dismissed as "imprecise language," U.S. Br. 12—the Federal Circuit has employed it some 30 times since 2001.[4] The FTC correctly recognizes that "[t]he Federal Circuit requires that claims be 'insolubly ambiguous' to be invalid as indefinite." *The Evolving IP Marketplace*, *supra*, at 11. And, contrary to what it says here, the PTO recognizes elsewhere that *Exxon* imposes a low threshold: "[T]he validity of a claim will be preserved if *some meaning* can be gleaned from the language."[5]

*Exxon*, the substance of which the government does not address, confirms that the Federal Circuit meant what it said. There, the court held that the term "for a period sufficient" was definite—even though the patent did not "quantify the 'period sufficient' limitation by reference to any specific period or range of periods," 265 F.3d at 1378—because the patent provided one example that satisfied this broad language, *id.* at 1378-79. The claims in *Exxon* did not establish "metes and bounds," much less by "clear notice." The government therefore is wrong that "[t]he Federal Circuit has most frequently used the relevant phrases"—i.e., "capable of construction" and "insolubly ambiguous"—"to express the insight that a patent claim may be sufficiently definite ... even though considerable study and analysis are required to discern its meaning." U.S. Br. 13. Rather, the Federal Circuit means by these "phrases" that claims are only indefinite in the extreme case when they provide "no guidance," *Power-One* v. *Artesyn Techs.*, 599 F.3d 1343,

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[4] Search of Westlaw's Federal Circuit database (CTAF) for all cases with "insolub!" and "ambig!" in the same sentence.

[5] Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7162, 7164 (Feb. 9, 2011) ("*PTO Guidelines*") (emphasis added).

1348 (Fed. Cir. 2010), and cannot "'be given any reasonable meaning,'" *Young* v. *Lumenis*, 492 F.3d 1336, 1346 (Fed. Cir. 2007).

This test is so firmly entrenched that the Federal Circuit has developed corollary doctrines based on it. Thus, the decision below holds that "a claim cannot be both indefinite and anticipated" because "[i]f a claim is indefinite, the claim, by definition, cannot be construed" and "[w]ithout a discernable claim construction, an anticipation analysis cannot be performed." Pet. App. 10a. By its terms, this analysis ties indefiniteness to whether claim language is capable of construction. The problem with doing so—as the Petition explains and the government does not address—is that claim construction does not necessarily identify the invention's "metes and bounds." Pet. 18-19. Claim construction commonly focuses on individual claim terms, not the claim as a whole. Sometimes the most a court can do is to define a claim term with a synonym, which is what happened here. See *id.* at 19; Pet. App. 52a; CAFC JA 44. Claim construction incorporates no requirement of definiteness—it simply asks the court to determine how a person of ordinary skill in the art understands disputed claim terms. *Phillips* v. *AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). The fact that a claim term has been construed therefore does not mean the claim is definite, contrary to the Federal Circuit's erroneous understanding.[6]

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[6] *E.g.*, *Bd. of Regents* v. *BENQ Am. Corp.*, 533 F.3d 1362, 1368 n.4 (Fed. Cir. 2008) (no indefiniteness where "we have been able to discern a construction"); *Energizer Holdings* v. *ITC*, 435 F.3d 1366, 1370-71 (Fed. Cir. 2006) ("A claim that is amenable to construction is not ... indefinite[]."); *Bancorp Servs.* v. *Hartford Life Ins.*, 359 F.3d 1367, 1372 (Fed. Cir. 2004) (same).

Ultimately, the proof is in the cases, and a survey shows that the Federal Circuit almost never finds indefiniteness. Of 48 indefiniteness decisions since *Exxon*, that court found indefiniteness only five times.[7] There is no reported case in the past 10 years in which the Federal Circuit affirmed a PTO determination that a patent claim is indefinite, and only one since the formation of the Federal Circuit in 1982.[8] In stark contrast, since 2000 the Federal Circuit has ruled for litigants asserting invalidity under 35 U.S.C. § 102(b), § 103, and § 112 doctrines other than indefiniteness between 41% and 54% of the time.[9] The amici supporting Applera's petition confirm that indefiniteness is a dead letter, as does a recent review of district court decisions. Altera Br. 11 & n.3 (discussing study by Laser). It is no wonder that Enzo could not identify a single meaningful application of definiteness by the Federal Circuit. BIO 27; see Reply Br. 7.

In short, the government has matters backwards. This is not a situation in which the Federal Circuit occasionally uses "imprecise" language while generally interpreting and applying the law properly. On the contrary, the Federal Circuit occasionally states the law correctly, see U.S. Br. 14-15, but most of the time it does not, and in application it almost never finds a claim indefinite. Following a pattern seen in other

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[7] Search of CTAF database for all cases with "claim!" and "indefinite!" in the same sentence; we excluded cases involving a technical indefiniteness defect such as failure to comply with 35 U.S.C. § 112 ¶ 6.

[8] *In re Corkill*, 771 F.2d 1496, 1500-01 (Fed. Cir. 1985). Search of CTAF for all appeals from the PTO since 2001 that include the term "indef!"

[9] Statistics compiled from the University of Houston's patent statistics database, http://www.patstats.org/Patstats2.html.

cases, the Federal Circuit took an accurate statement of law—that insolubly ambiguous claims are indefinite—and rewrote it into an exclusive test that is erroneous: "*Only* claims 'not amenable to construction' or 'insolubly ambiguous' are indefinite." *Datamize*, 417 F.3d at 1347 (emphasis added). The Court has corrected such errors before, and should do so here. *KSR Int'l* v. *Teleflex*, 550 U.S. 398, 415, 418-19 (2007) ("We begin by rejecting the rigid approach of the Court of Appeals."; "Helpful insights ... need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents."). It is broadly understood among patent lawyers that indefiniteness has drifted into desuetude, an intolerable state of affairs that incentivizes broad and imprecise claim drafting to the detriment of the public. Review is appropriate now and in this case: "If this Court does not act, there will be little or no incentive for future litigants to raise the issue in the lower courts." Altera Br. 18-19.

## II. THE FEDERAL CIRCUIT'S INTERPRETATION OF § 112 CONFLICTS WITH THE PTO'S.

The petition demonstrates that the PTO and the Federal Circuit employ different tests for indefiniteness. Pet. 23-26; Reply 8-9. The government responds that "the PTO's recently published guidelines for examiners ... make clear [that] the agency conducts essentially the same definiteness inquiry that courts apply." U.S. Br. 16. But the PTO Guidelines actually say something quite different: "Claims under examination are evaluated with a different standard than patented claims to determine whether the language is definite." 76 Fed. Reg. at 7164 (capitalization and emphasis omitted). The FTC agrees. See *The Evolving IP Marketplace*, *supra*, at 11 ("[t]he

PTO ... has adopted a lower threshold of ambiguity"). This is why the government must admit that "[t]he PTO does instruct agency examiners to employ 'a lower threshold of ambiguity when reviewing a pending claim for indefiniteness' than that used by the Federal Circuit." U.S. Br. 17.

Moreover, the PTO recognizes elsewhere that the Federal Circuit is not using the standard that the government advocates here. The *PTO Guidelines* say that a claim should be rejected during examination "if the metes and bounds of the claimed invention are not clear." 76 Fed. Reg. at 7164. That is the standard that the government says should govern in the Federal Circuit, see U.S. Br. 8, yet the PTO says in its *Guidelines* that the Federal Circuit is employing a less demanding standard. 76 Fed. Reg. at 7164. Paradoxically, the government also seeks to justify the use of disparate standards, U.S. Br. 17—an assertion at odds with its claim that the PTO and the Federal Circuit are using the same standard, *id.*—but the PTO and the Federal Circuit are applying the same statutory language, and in no other domain does the PTO assert that its legal test can diverge from the Federal Circuit's. See Pet. 24 & n.10; Reply 8-9. Plainly, the language of the statute does not have a different meaning depending whether it is to be applied in the PTO or the courts. This stark inconsistency confirms that clarity from this Court is sorely needed.

## III. THE DECISION BELOW IS A GOOD VEHICLE FOR RESOLVING THESE ISSUES.

As the petition explains, this case presents a striking application of the Federal Circuit's standard. Pet. 26-29. The patents employ broad functional language and terms of degree—techniques this Court and the PTO warn are particularly susceptible to indefinite-

ness—at the very point of alleged novelty. *Id.* at 27 & n.12; *PTO Guidelines*, 76 Fed. Reg. at 7164-65. Rather than providing "clear notice" of "metes and bounds," these patents give mere examples. Pet. 11-12, 21-22, 26-27. This, presumably, is why Enzo felt compelled to argue that definiteness does not require clear notice of boundaries. BIO 15 (claims need not "fix the 'metes and bounds' of the invention"); *accord id.* at 3, 12, 16. Instead, Enzo advances the novel argument that patent claims merely distinguish an invention from the prior art. *Id.* at 2-3. Tellingly, the government does not defend Enzo's unprecedented rule, and the formulation embraced by the government—"clear notice of the [invention's] metes and bounds," U.S. Br. 8—is flatly at odds with Enzo's.

Instead, the government responds that this case is an unsuitable vehicle because "the court of appeals did not use either the phrase 'insolubly ambiguous' or the phrase 'capable of construction.'" U.S. Br. 15. This argument is curious, given the government's insistence that the focus should be on underlying "principles" rather than "those phrases." *Id.* at 13. In any event, the court indeed embraced these concepts: It held that "[i]f a claim is indefinite, the claim, by definition, cannot be construed," and on that basis developed a false syllogism that anticipation is impossible where there is indefiniteness. Pet. App. 10a. Moreover, the court relied on established Federal Circuit authorities which hold that claims are indefinite only when they are "not amenable to construction or are insolubly ambiguous." Reply Br. 6 (quotation marks omitted). More egregious still, the court was satisfied because the claims "provide at least some guidance," Pet. App. 14a—a far cry from "particularly pointing out and distinctly claiming."

The government further cautions the Court to avoid the "highly technical" facts of this case, U.S. Br. 15, vouching that one of ordinary skill in the art would understand the claims, *id.* at 18-22. This is wrong for the reasons we have explained, see Pet. 26-29, and it is beside the point. The issue here is the erroneous legal standard that controls in the Federal Circuit, and it is that fundamental legal error that warrants this Court's time and attention. Just as it did in *eBay* and *KSR*,[10] the Court should grant certiorari to correct the Federal Circuit's erroneous test for a key patent law doctrine and—as it did in *eBay* and has done in numerous cases in other contexts—the Court may remand for the lower courts to apply that standard in this case.

In any event, this case is particularly suitable for review because it is the unusual instance in which a district court did hold claims indefinite. The court reviewed Enzo's own expert testimony explaining that "'[i]t's probably in the hands of the experimenter'" to determine the bounds of substantiality, a boundary that "'may mean different things to different people.'" Pet. App. 57a; *id.* at 60a. The court understandably found it "instructive" that two scientists, both Enzo executives, could not "conjecture a means of determining substantiality of interference." *Id.* at 56a, 58a. Most telling, Enzo employed different experts for infringement and validity, who took conflicting views on the reach of the claim term—one interpreting it broadly to capture infringement, the other narrowly to avoid invalidity, *id.* at 64a—which is a tactic that has become common because of the Federal Circuit's indefiniteness doctrine, see Yahoo

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[10] *See KSR*, 550 U.S. 398; *eBay* v. *MercExchange*, 547 U.S. 388 (2006).

Br. 14-16. The court construed the claim terms, while correctly recognizing them to be an "illusory yardstick." Pet. App. 60a. Enzo dared the court to find the terms indefinite—"[T]he Court should faithfully interpret 'substantially interfering' and if it's indefinite, then we'll have to live with that," CAFC JA 1644-47—and the district court was the rare one to do so.

"For a decade," Enzo acknowledges, "the Federal Circuit has employed its current standards without meaningful dispute or dissent." BIO 25. And this Court has not directly considered definiteness since World War II. The patent community is watching this case to see whether the last nail is in the coffin. Patent practitioners, litigants, the public and innovation all will suffer if it is no longer possible to tell with meaningful clarity what a patent claim covers.

## CONCLUSION

For the foregoing reasons, and those set forth in the petition and reply brief, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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